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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/597,328	01/10/2008	Abdul Waseh Basit	33327.001	9321

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Intellectual Property Dept.
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EXAMINER	
SHOMER, ISAAC	
ART UNIT	PAPER NUMBER
1612	

NOTIFICATION DATE	DELIVERY MODE
08/18/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket-ip@dewittross.com

Office Action Summary	Application No.	Applicant(s)	
	10/597,328	BASIT ET AL.	
	Examiner	Art Unit	
	ISAAC SHOMER	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 June 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) *18 and 19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20 July 2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Amendments

The examiner clarifies that the claims to be examined were those filed as of 20 July 2006. While claim sets filed at a later date appear in the file wrapper, such claims appear merely to be copies from the WIPO publication WO 2005/070391 A3, and do not reflect the amendments to the claims made upon entry to the national phase under 35 U.S.C. 371.

Election/Restrictions - Groups

Applicant's election with traverse of Group I, claims 1-17 in the reply filed on 17 June 2010 is acknowledged. The traversal is on the ground(s) that the examiner must examine claims drawn to a method for making a product and a product under PCT rules. This is not found persuasive because the groups still lack unity as they lack an inventive step in view Satturwar et al. (Journal of Microencapsulation, Vol. 19 No. 4, 2002, pages 407-413) in view of Kim et al. (Journal of Microencapsulation, 2002, Vol. 19, No. 6, pages 811-822) as evidenced by Bontemps et al. (US Patent 4,897,267), as shown below.

Claims 18 and 19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 17 June 2010.

Election/Restrictions - Species

Applicant's election of prednisone as the specie of active agent, and methacrylate as the specie of delivery vehicle in the reply filed on 17 June 2010 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Prednisone is not in any of the claims, but prednisolone is recited. As one is a prodrug of the other, the examiner withdraws the election between prednisone and prednisolone and expands the search to include both species.

Information Disclosure Statement

The three non-patent documents on the information disclosure statement filed 20 July 2006 have not been provided. As such, the information disclosure fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file. The US patent document on this information disclosure statement has been considered, non-patent literature documents have not been considered.

Claim Objections

Claim 7 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of previous claim 1. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 7 requires the limitations of claim 1 wherein the vehicle is a polymer which enables pH-dependent and/or pH independent release. Since all types of release may be considered as either pH dependent or independent, it does not appear that this limitation excludes any vehicles, and as such does not further limit claim 1.

Claim 13 is objected to because of the following informalities: Applicant should insert a space between "or and budesonide," as of the second line of claim 13.

Claim Rejections - 35 USC § 112 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 11 and 12 contain the following trademark/trade names: Eudragit L100, Eudragit L 100-55, Eudragit S100, Eudragit P 4135, and Eudragit RS100. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not

comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name Eudragit RS100 is used to identify/describe copolymers of methacrylate and acrylate comprising quaternary ammonium side groups and, accordingly, the identification/description is indefinite. In the present case, the trademark/trade name Eudragit S and L is used to identify/describe copolymers of methacrylate and acrylate comprising carboxylate side groups (anionic) and, accordingly, the identification and description is indefinite. See also MPEP 2173.05(u).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 7-12, and 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Satturwar et al. (Journal of Microencapsulation, Vol. 19 No. 4, 2002, pages 407-413) in view of Kim et al. (Journal of Microencapsulation, 2002, Vol. 19, No. 6, pages 811-822) as evidenced by Bontemps et al. (US Patent 4,897,267).

Satturwar et al. (hereafter referred to as Satturwar) teaches a method for making microspheres of diclofenac in Eudragit RL comprising the use of acetone, isopropyl alcohol, and liquid paraffin, as of Satturwar, page 407, abstract. In the method of Satturwar, Eudragit RL was dissolved in an acetone-isopropyl alcohol solution, and the active agent was added, followed by the solution being sprayed into liquid paraffin, and

removal of the solvent at 60 C, as of Satturwar, paragraph bridging pages 408 and 409. Particles were sized from 15-25 microns, as of Satturwar, page 410, Table 1.

Satturwar does not teach a surfactant.

Kim et al. (hereafter referred to as Kim) teaches microspheres comprising an Eudragit RL and Eudragit RS in an oil in oil emulsion and methods of making thereof, wherein the particles are sized from 9.5 to 13.2 microns, as of Kim, page 811, abstract. In the method of Kim, the active agent and Eudragit were dissolved in an acetonitrile/dichloromethane mixture, then emulsified into corn oil containing 2% Span 80 surfactant (HLB 4.3, as of Bontemps et al, column 5 line 29), followed by evaporation of organic solvent, as of Kim, page 813, top two paragraphs.

It would have been prima facie obvious for one of ordinary skill in the art to have used a surfactant, as taught by Kim, in the method of Satturwar. This is because surfactants are known in the art for use in oil in oil emulsions for the manufacture of Eudragit microparticles, as taught by Kim. As such, the skilled artisan would have been motivated to have predictably utilized the surfactant Span 80 for the purposes of predictably making Eudragit microparticles from an oil in oil emulsion created by emulsifying an organic solvent in an oil with a reasonable expectation of success. Generally, it is *prima facie* obvious to select a known material for incorporation into a composition, based on its recognized suitability for its intended use. See MPEP 2144.07.

Claims 4-6 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Satturwar et al. (Journal of Microencapsulation, Vol. 19 No. 4, 2002, pages 407-413) in view of Kim et al. (Journal of Microencapsulation, 2002, Vol. 19, No. 6, pages 811-822) as evidenced by Bontemps et al. (US Patent 4,897,267) as applied to claims 1-3, 7-12, and 14-16 above, and further in view of Bontemps et al. (US Patent 4,897,267).

The above references teach a method of making Eudragit microparticles comprising an active agent by an oil in oil emulsion. See the above rejection. The microparticles may include the surfactant Span 80, as of Kim, page 813, top two paragraphs.

The above references do not teach sorbitan monoleate and sorbitan dioleate.

Bontemps et al. (hereafter referred to as Bontemps) teaches a method of making microparticles, as of Bontemps, abstract. In said method, a polymer and an active agent were dissolved in acetone and cooled to 0 degrees C, as of Bontemps, column 4 lines 40-51. Said solution was combined with liquid paraffin, and the solvent was removed, as of Bontemps, column 4 line 52 to column 5 line 5. The surfactant known by the trade name Arlacel 83 (sorbitan sesquioleate, which has a HLB of 3.7) may be used as of Bontemps, column 5 line 28. Said method is that of an emulsion, as of Bontemps, column 4 line 66.

It would have been prima facie obvious for one of ordinary skill in the art to have used the surfactant sorbitan sesquioleate as the surfactant in the method of the above references. This is because said surfactant is known for making polymer microparticles

in an emulsion of an organic solvent in liquid paraffin (an oil in oil emulsion), as of Bontemps above. As such, the skilled artisan would have been motivated to have used sorbitan sesquioleate as the surfactant in an oil in oil emulsion to have predictably made microparticles comprising an active agent with a reasonable expectation of success. Generally, it is *prima facie* obvious to select a known material for incorporation into a composition, based on its recognized suitability for its intended use. See MPEP 2144.07.

Satturwar teaches the combination of the solvents with liquid paraffin at 60 C, as of Satturwar, page 408, last paragraph. Bontemps teaches the combination of the solvent phase with the liquid paraffin phase at 0 C, as of Bontemps, column 4 lines 52-57. As such, the skilled artisan would have recognizes that the phases could have been combined at temperatures ranging from 0 C to 60 C, which overlaps with the temperature range of 10-30 C as of claim 17.While the prior art does not disclose the exact claimed values, but does overlap: in such instances even a slight overlap in range establishes a *prima facie* case of obviousness. In re Peterson, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003).

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Satturwar et al. (Journal of Microencapsulation, Vol. 19 No. 4, 2002, pages 407-413) in view of Kim et al. (Journal of Microencapsulation, 2002, Vol. 19, No. 6, pages 811-822) as evidenced by Bontemps et al. (US Patent 4,897,267) as applied to claims 1-3, 7-12, and 14-16 above, and further in view of Hersh (US Patent 6,303,651).

The above references teach a method of making Eudragit microparticles comprising an active agent by an oil in oil emulsion. See the above rejection. The active agent used by Satturwar is diclofenac, which is an anti-inflammatory drug for oral administration, as of Satturwar, page 407, last paragraph.

The above references do not teach prednisone.

Hersh teaches that prednisone is a known agent with anti-inflammatory properties that can be administered orally, as of Hersh, column 3 lines 54-57.

It would have been prima facie obvious for one of ordinary skill in the art to have combined prednisone, as of Hersh, with diclofenac, as of Sattuwar, as both drugs are predictably anti-inflammatory drugs known for oral administration with a reasonable expectation of success. Generally, it is *prima facie* obvious to combine two compositions, each of which is taught by the prior art to be useful for same purpose, in order to form a third composition to be used for the very same purpose. The idea for combining them flows logically from their having been individually taught in the prior art. See MPEP 2144.06.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ISAAC SHOMER whose telephone number is (571)270-7671. The examiner can normally be reached on 8:00 AM - 5:00 PM Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on (571)272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/I. S./
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612